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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,151

01/15/2004

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/760,151	Applicant(s) FILSOUFI, FARZAN	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15-19 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,12,13,15-19 and 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 3, 4, 10, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 22, 2005.

Claim 18 invokes a Section 112, sixth paragraph interpretation in that it sets forth “fixation means for attaching.” However, claim 19 does not invoke Section 112, sixth paragraph because it is limited by sufficient structure; see MPEP 2181 to 2186.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7-9, 12, 16-19, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dardik et al (US 3,988,782). Dardik anticipates the claim language where the graft of Dardik is considered to be at least semi-rigid to the extent claimed because it is hardened and even provided with a backing to improve its integrity (see column 7, lines 18-21). In other words, it is capable of being attached to a leaflet to the extent that the functional language implies; see Figures 5 and 6 and column 5, line 15 to column 6, line 61.

It is noted that a wide variety of rigidities is considered suitable for the presently disclosed invention ranging from rigid to flexible and elastic; see paragraph [0042].

Therefore, the Examiner asserts that the Dardik material is rigid to semi-rigid to the extent required by the claims because it reasonably appears to be able to function as claimed in that it is to be used in a similar environment.

With regard to claim 18, the suture of Dardik is a fixation means as claimed; see claim 19.

With regard to claim 43, the claim is indefinite in scope but the disclosed invention reasonably appears to be identical to that disclosed by Dardik. Therefore, the claimed invention reasonably appears to be identical to Dardik.

Claims 1, 5, 6-9, 12, 16-19, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Saxon (US 5,725,577). Saxon anticipates the claim language in that the device thereof would be inherently capable of functioning as the functional language implies; see Figure 6 and the abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dardik et al (US 3,988,782) alone. Dardik meets the claim language as explained in the Section 102 rejection utilizing Dardik, but fails to disclose the particular dimensions as claimed. However, when the only difference between the prior art and the claims is a recitation of some relative dimensions and the prior art device would not

perform differently than the claimed device, the claimed device would have been considered *prima facie* obvious to an ordinary artisan. The following is an excerpt from MPEP 2144.04:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Response to Arguments

Applicant's arguments filed November 29, 2007 have been fully considered but they are not persuasive.

The Applicant argues that Dardik is incapable of use in vascular surgery to withstand pulsatile pressures; see the argument beginning on page 8 of the response. However, Dardik states that the material is for replacement of "vessels, ducts, intestines, and urinary bladders"; see the abstract. Dardik goes on to states that "coverings are needed for . . . heart valves" (see column 1, lines 24-25). Dardik adds that the disclosed material is for "replacement of non-pulsatile tubular members" but can be used as "a reinforcement of a section of artery or a vein" (see column 4, lines 8-12). Therefore, a reasonable interpretation is that the material is not to be used by itself as a blood vessel replacement but can be used as a patch on a blood vessel or as a reinforcement therefor. For this reason, the material disclosed would be suitable as a leaflet reinforcement.

Next, the Applicant argues that Dardik's device is not enabled "for a heart valve prosthetic device"; see page 10 of the response. However, it is noted that Dardik teaches a wide variety of uses including the use as a patch on blood vessels and as reinforcements for blood vessel. For this reason, the Examiner asserts that Dardik taught how to use the device to reinforce a leaflet to extent required in that the exact use need not be taught for the device to be enabled.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Art Unit: 3774

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774